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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
(SAN JOSE DIVISION)

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO, INC. (Defendant only), MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.,

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF/PSG

GILEAD SCIENCES, INC.'S [PROPOSED] FINDINGS OF FACT AND CONCLUSIONS OF LAW

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I. [PROPOSED] FINDINGS OF FACT

A. Litigation at Hand

1. Gilead filed its complaint for declaratory judgement of invalidity of U.S. Patent Nos. 7,105,499 ("the '499 patent") and 8,481,712 ("the '712 patent") on August 30, 2013.

2. The '499 patent issued on September 12, 2006. (EX-0001.)

3. The '712 patent issued on June 9, 2013. (EX-0002.)

4. The '499 and '712 patents claim priority to Merck's PCT Application (WO 02/057425), filed on January 18, 2002. (EX-0808.)

5. Gilead's drug, sofosbuvir, is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active 2' methyl up, 2' fluoro down uridine analog triphosphate for the treatment of HCV. (EX-0003.0019.)

6. Sofosbuvir was discovered by Dr. Michael Sofia, Jinfa Du, and Peiyuan Wang at Pharmasset, Gilead's predecessor company. (Trial Tr. at 231:15-18 (Sofia).)

7. Gilead acquired Pharmasset in 2011. (Trial Tr. at 211:24-212:3 (McHutchison).)

8. Prior to the approval of sofosbuvir in 2013, Gilead conducted clinical trials for sofosbuvir to assess the safety and efficacy of the compound. (Trial Tr. at 212:7-20 (McHutchison).)

9. Gilead obtained FDA approval for sofosbuvir (Sovaldi®) in 2013. (Trial Tr. at 220:10-23 (McHutchison).)

10. Sofosbuvir was the first drug approved to treat certain HCV genotypes without the need for co-administration of interferon. (Trial Tr. at 207:18-20 (McHutchison).)

11. Gilead obtained FDA approval for a single-tablet combination therapy of sofosbuvir and ledipasvir (Harvoni®) in 2014. (Trial Tr. at 223:7-25 (McHutchison); EX-1489.)

12. Harvoni® is the first combination pill approved to treat HCV genotype 1 infection and was the first approved product that does not require administration with interferon or ribavirin. (Trial Tr. at 223:7-25 (McHutchison).)

B. Merck-Pharmasset Interactions in 2004: Philippe Durette's Actions in Obtaining Claims Covering PSI-6130

1. Chronology of Merck's Improper Use of Pharmasset Confidential Information to Draft Its Patent Claims

13. On January 29, 2001, Pharmasset entered into a Non-Disclosure Agreement with Merck. (EX-2298.) The purpose of the Non-Disclosure Agreement was to permit disclosure of "certain confidential and proprietary information concerning discovery and development of antiviral agents against flaviviruses in particular hepatitis C virus (HCV)" for the purpose of "evaluating a possible business relationship between the Parties." (EX-2298.0002.)

14. Pursuant to the Non-Disclosure Agreement, Merck agreed to hold the confidential information disclosed to it by Pharmasset in confidence and to not disclose any confidential information to any third party without the prior written authorization of Pharmasset. (EX-2298.0003, ¶ 5.) Merck also agreed that it would not use Pharmasset's confidential information for any purpose other than for evaluating a potential collaboration with Pharmasset. (EX-2298.0003, ¶ 6.)

15. On August 22, 2003, Pharmasset and Merck amended their Non-Disclosure Agreement to include the disclosure of confidential information relating to HIV, again for purposes of evaluating a potential collaboration. (EX-1241.0001.) The August 22, 2003 Amendment explicitly stated that all terms and conditions of the January 29, 2001, Non-Disclosure Agreement shall remain in full force and effect. (*Id.*)

16. From 2003 to 2004, Merck evaluated Pharmasset's PSI-6130 nucleoside analog invented by Jeremy Clark under the auspices of negotiating a potential collaboration agreement. (Trial Tr. at 1430:12-18 (Demain); EX-0089; EX-0090.)

17. On October 23, 2003, Pharmasset and Merck executed a Material Transfer Agreement authorizing Merck to conduct testing and evaluation of ten Pharmasset nucleosides, including PSI-6130. (EX-1231.0006.) Pursuant to the Material Transfer Agreement, Merck agreed to use the disclosed nucleoside compounds only for the testing and evaluation set forth in

the Agreement. (EX.1231.0007.) The Material Transfer Agreement explicitly prohibited Merck from determining the chemical structure of the nucleosides provided for testing. (*Id*.)

18. On December 12, 2003, Pharmasset and Merck amended their Material Transfer Agreement to include further evaluation of PSI-6130 as an HCV inhibitor. (EX-1231.0003.)

19. On December 10, 2003, the parties exchanged a first draft of a term sheet regarding HCV collaboration. (EX-2328.)

20. In January 2004, Merck requested that certain information concerning the structure of PSI-6130 be shared with a Merck "firewalled" chemist, Dr. Wallace Ashton. (EX-2302.0003; EX-0183.0001.)

21. On February 4, 2004, Pharmasset provided information to Dr. Ashton, disclosing that PSI-6130 was a cytosine base containing nucleoside, without a N=O bond, and with a 5' hydroxyl group. (EX-0046.001; EX-0047.0001-2.)

22. The structure of PSI-6130 was not publicly known at the time. (Tr. at 428:20-429:2 (Roemer); EX-0153.)

23. In March 2004, Merck arranged to have Dr. Philippe Durette participate on a conference call with Pharmasset during which Merck was aware that the structure of PSI-6130 would be disclosed. (Trial Tr. at 355:22-360:15 (Durette); EX-0153.) At that point, Pamela Demain noted in an e-mail that "Pharmasset has not yet permitted us to review the structure of PSI-6130," but that, "[a]s a first step, Phil Durette will view the structure during a patent due diligence meeting on March 17, [2004]." (EX-0153.0001.)

24. At trial, Dr. Durette testified that Ms. Demain asked him to attend the due diligence meeting with Pharmasset on March 17, 2004. (Trial Tr. at 355:17:23, 375:12-19 (Durette).) Ms. Demain, however, testified at trial that she did not ask Dr. Durette to be on the March 17, 2004, call with Pharmasset. (Trial Tr. at 1404:14-1405:8 (Demain).) Merck provided no explanation for this pointedly inconsistent testimony.

25. Dr. Durette was Merck's patent attorney in charge of prosecuting patents for nucleoside analogs for the treatment of HCV synthesized during the Merck-Isis collaboration. (Trial Tr. at 328:21-24 (Durette).)

26. Dr. Durette was aware of the possibility that the information he learned about Pharmasset's PSI-6130 nucleoside analog compound might overlap with the subject matter of his prosecution docket, which related to Merck's nucleoside analog compounds, thereby creating a conflict. (Trial Tr. at 354:14-355:16; 364:11-365:11, 375:7-23 (Durette).)

27. Before the March 17, 2004, phone call, Merck had been provided samples of PSI-6130 in a blinded form for evaluation, coded as PM-03. (EX-0090.) Merck knew that PSI-6130 targeted the NS5B polymerase enzyme. (EX-0090; EX-2300; EX-2299.)

28. Dr. Durette's applications for the Merck-Isis collaboration claimed what were alleged to be NS5B nucleoside polymerase inhibitors. (EX-0808.)

29. On March 17, 2004, Dr. Durette participated in a conference call with Pharmasset on which he learned the structure of PSI-6130. (Trial Tr. at 431:7-14 (Roemer); Trial Tr. at 347:9-22 (Durette); EX-2098.)

30. While on the conference call and before Pharmasset revealed the structure of PSI-6130, Dr. Durette did not tell Pharmasset that he was prosecuting patents in the same field of HCV nucleoside analogs. (Trial Tr. at 435:7-12 (Roemer); EX-2098; Trial. Tr. at 382:8-383:6.)

31. During the conference call, Mr. Roemer confirmed that all Merck attendees, including Dr. Durette, were under the "firewall" of the Confidentiality Agreement. (Trial Tr. 382:8-18 (Durette); Trial Tr. at 434:1-24 (Roemer); EX-2098.0002.)

32. Dr. Durette was not "firewalled" by virtue of his involvement in prosecuting the Merck-Isis patents.

33. Dr. Durette lied to Pharmasset about being firewalled.

34. Pharmasset and Merck did not enter into a licensing arrangement regarding a license to PSI-6130 in 2004. (Trial Tr. at 1435:5-10 (Demain).)

35. Jeremy Clark's patent application disclosing the structure of PSI-6130 published on January 13, 2005. (EX-0155.)

36. On February 1, 2005, Dr. Durette cancelled all then-pending claims of the application that would ultimately issue as the '499 patent. (EX-0156.0004.)

37. The pending claims had not yet been rejected by the patent examiner, and the examiner had not asked Dr. Durette to narrow the claims. (Trial Tr. at 372:18-23 (Durette).)

38. Dr. Durette added two new, narrower claims, which covered the structure of PSI-6130. (EX-0156.0002-.0003.)

39. The two narrowed claims issued as claims 1 and 2 of the '499 patent. (EX-0156.0004.)

40. Dr. Durette represented to the U.S. Patent and Trademark Office ("USPTO") that the new claims "do not introduce new matter into the application since they are fully supported by Applicants' specification." (EX-0156.0004.)

41. Dr. Durette's representation to the USPTO was not true. (Trial Tr. at 732:15-22 (Secrist).)

42. Merck did not make a compound with the same structure as PSI-6130, nor test such a compound, nor use such a compound, during the Merck-Isis collaboration that ended in 2003. (Bennett Dep. Tr. (EX-2381) at 123:15-124:01, 124:06-21; Duffy Dep. Tr. (EX-2382) at 46:22-25; Trial Tr. at 576:1-22 (Seeger); ECF No. 300.)

43. Isis did not make a compound with the same structure as PSI-6130, nor test such a compound, nor use such a compound, during the Merck-Isis collaboration that ended in 2003. (Bennett Dep. Tr. (EX-2381) at 123:15-124:01, 124:06-21; Trial Tr. at 576:1-22 (Seeger); ECF No. 300.)

44. Merck and Isis knew that whether any given compound could inhibit the NS5B polymerase enzyme was unpredictable. (Carroll Dep. Tr. (EX-2379) at 123:18-123:25, 164:6-

10, 165:23-25, 166:7-16, 168:10-16, 168:19-169:5, 181:12-182:1, 196:15-17, 196:2-198:4, 198:5-8, 198:12-24, 199:1-17; Bennett Dep. Tr. (EX-2381) at 77:20-78:23.)

45. Merck and Isis knew that whether any given compound could treat HCV infection was unpredictable. (Carroll Dep. Tr. (EX-2379) at 123:18-123:25, 164:6-10, 165:23-25, 166:7-16, 168:10-16, 168:19-169:5, 181:12-182:1, 196:15-17, 196:2-198:4, 198:5-8, 198:12-24, 199:1-17; Bennett Dep. Tr. (EX-2381) at 60:13-17; 60:18-21;77:20-78:23.)

46. Merck and Isis knew that in order to determine if any given compound had anti-HCV activity, that compound must be tested in either the NS5B polymerase assay or the replicon assay. (Carroll Dep. Tr. (EX-2379) at 167:03-06; Bennett Dep. Tr. (EX-2381) at 77:20-78:23.)

47. Merck did not make a compound with the same structure as PSI-6130 until August 2005, seven months after Mr. Clark's patent application published, and six months after filing a patent claim to cover it. (Trial Tr. at 1130:12-17; Duffy Dep. Tr. (EX-2382) at 46:22-25.)

48. Dr. Durette waited until Pharmasset published the structure of PSI-6130 before claiming Pharmasset's invention that he learned of during the March 17, 2004, conference call. (Trial Tr. at 369:24-374:4, 417:1-19 (Durette).)

49. Dr. Durette did not inform the patent examiner that he learned of the structure of PSI-6130 from Pharmasset, and learned that PSI-6130 was "very active" against HCV, from the publication of the Clark application, not from work done at Merck. (Trial Tr. at 415:1-9, 420:20-23 (Durette).) Nor did Dr. Durette inform the examiner that neither Merck nor Isis had ever made nor tested a compound covered by the claims he filed in February 2005.

50. At trial Dr. Durette acknowledged that he had a never-ending duty of candor to the Patent Office. (Trial Tr. at 420:9-11.)

2. Dr. Durette Gave Two Different, Inconsistent Explanations for His Actions at Trial and at His Deposition

51. When questioned in this case about the March 2004 call on which he first learned the structure of PSI-6130, Dr. Durette initially attempted to cover up his conduct.

52. When originally asked about the March 17, 2004 telephone call at his deposition, Dr. Durette unequivocally denied ever having been on such a call. (Durette Depo. Tr. (EX-2388) at 30:21-31:03.) He did not say that he did not remember a call or that he could not be sure, but instead definitively stated that he was "positive" that the structure of PSI-6130 was never revealed to him and that he did not see it until it later published. (*Id.* at 31:04-31:10.)

53. When asked how he could be so sure, eleven years later, that he was not on the March 2004 call, Dr. Durette explained that he "would not have been privy to any revelation of the structure . . . as a patent attorney working on a related docket." (*Id.* at 38:01-38:08.) Dr. Durette explained that it was against Merck's company policy to have a Merck patent prosecutor participate in licensing discussions in a related area. (*Id.* at 38:25-39:07.) He went even further and testified under oath that his presence on the call would have been inappropriate because "it would have tainted [his] judgment as to what claims to pursue in the Merck/Isis collaboration." (*Id.* at 38:21-38:24.)

54. Dr. Durette was not aware at the time of his deposition that Pharmasset's Alan Roemer had taken contemporaneous notes of that March 17, 2004 phone call. (Trial Tr. at 380:22-25 (Durette).) It was not until becoming aware of those notes that Dr. Durette began to backtrack on the definitive statements from his deposition.

55. When asked about the March 17, 2004, phone call at trial, Dr. Durette stated that he had been mistaken at his deposition and acknowledged that he was present on the call. (Trial Tr. at 344:1-345:7, 347:9-22 (Durette).)

56. Dr. Durette provided no credible explanation for how he could have testified at his deposition that he was positive he was not on the call.

57. The most reasonable explanation for Dr. Durette's inconsistent testimony at deposition and trial is that his deposition testimony was not truthful and that he later acknowledged his presence on the call at trial only after recognizing that there was evidence demonstrating that he had been there.

58. The inconsistency between Dr. Durette's explanations about the March 2004 call at deposition and at trial calls into question the credibility of the entirety of Dr. Durette's testimony.

59. Dr. Durette's trial testimony that Ms. Demain, Merck's director of corporate licensing, asked him to attend the March 17, 2004 call is also inconsistent with Ms. Demain's trial testimony that she did not ask him to attend the call. (Trial Tr. at 355:17:23, 375:12-19 (Durette), 1404:14-1405:8 (Demain).)

60. This inconsistency is further evidence demonstrating that Dr. Durette's testimony is not credible.

61. Ms. Demain testified that she did not ask Dr. Durette to attend the March 17, 2004, call with Pharmasset, and did not know in March 2004 that Dr. Durette was a Ph.D. chemist assigned to prosecute the Merck-Isis patent portfolio. (Trial Tr. at 1434:14-1435:4 (Demain).)

62. In light of the contemporaneous e-mail from Ms. Demain indicating that Dr. Durette would be on the call and would learn the structure of PSI-6130 (EX-0153.0001), Ms. Demain's testimony on this point is not credible.

63. It is also not credible that Ms. Demain, a corporate licensing director at Merck, would have failed to inquire whether Dr. Durette, a patent prosecutor, had a potential conflict and would have failed to confirm that Dr. Durette was within the firewall and thus could receive Pharmasset confidential information, before allowing Dr. Durette to attend the call and learn the structure of PSI-6130.

64. In his trial testimony, Dr. Durette attempted to justify his presence on the call by suggesting that it was merely a "potential conflict" or "potential taint," and that it would depend on what he did with the information later. (Trial Tr. at 350-54 (Durette).) In support of this, Dr. Durette asserted at trial that, while he knew PSI-6130 was a nucleoside inhibitor, he did not know that PSI-6130 was an inhibitor of the NS5B polymerase. (Trial Tr. at 364:13-18, 365:13-21, 367:13-368:6 (Durette).)

65. Dr. Durette's testimony is contradicted by documentary evidence that demonstrates non-firewalled individuals at Merck knew that PSI-6130 was an inhibitor of the NS5B polymerase. (EX-0090; EX-2300.) Well before the March 17, 2004, phone call, Merck had conducted blinded testing on PSI-6130 and had learned it was very active in inhibiting the NS5B polymerase enzyme. (EX-0090.)

66. In addition, the term sheet attached to the e-mail from Ms. Demain informing the Merck team that Dr. Durette would learn the structure of PSI-6130 states that: "Until then, this amount [of the proposed license] is based on the following assumptions: . . . That lead compound **PSI-6130** . . . is a chain terminator of HCV polymerase . . . ." (MERCK0187433 at 34 (emphasis in original).)

67. Dr. Durette's trial testimony that he did not recognize learning the structure of PSI-6130 conflicted with his work prosecuting the Merck-Isis patent is not credible, at least in light of his deposition testimony, but also in light of Merck's testing of the blinded PSI-6130 and the statements in the term sheet about nucleoside inhibitors. (EX-0090; MERCK0187433; Trial Tr. at 358:1-20 (Durette).)

68. The most reasonable inference drawn from these facts is that Dr. Durette, a Ph.D. chemist, understood that PSI-6130 had the same mechanism of action as the nucleoside compounds for which Dr. Durette was seeking patent protection, and that there was great potential that learning the structure of the compound would create a conflict of interest for him.

Despite this, he proceeded to attend the March 17, 2004, call anyway, knowing he would learn of the full structure of PSI-6130.

69. Dr. Durette recognized that his presence on the call was improper.

70. Dr. Durette's use of the information he learned on the call in prosecuting the claims of the application leading to the '499 patent was improper.

3. Dr. Durette's Improper Claim Amendments Based on Confidential Information Learned from Pharmasset

i. Acts Concerning to the '499 Patent Application

71. After the structure of PSI-6130 was disclosed to Merck on the March 17, 2004, call, Mr. Roemer again confirmed that all Merck attendees, including Dr. Durette, were under the "firewall" of the Confidentiality Agreement. (Trial Tr. 382:8-18 (Durette); Trial Tr. at 434:1-24 (Roemer); EX-2098.0002.)

72. Dr. Durette was not "firewalled" as he continued to prosecute the Merck-Isis patents.

73. Dr. Durette, to comply with Merck's obligations under the Non-Disclosure Agreement (EX-2298, EX-1241), was required to recuse himself from any further prosecution of the Merck/Isis patent applications.

74. As Dr. Durette admitted at his deposition, it was against Merck's company policy to have a Merck patent prosecutor participate in licensing discussions in a related area, and his presence on the call "would have tainted [his] judgment as to what claims to pursue in the Merck-Isis collaboration." (Durette Dep. Tr. (EX-2388) at 38:9-39:07.)

75. Merck has not provided any credible explanation of why Dr. Durette was not firewalled from further prosecution of the Merck-Isis patent applications after learning the structure of PSI-6130.

76. Dr. Durette's continued prosecution of the Merck-Isis patent applications violated Merck's confidentiality obligations to Pharmasset.

77. Dr. Durette claimed at trial that he "could have filed that narrowing application at any point" to more specifically claim PSI-6130 at any time because it was already disclosed in the 2001 application. (Trial Tr. at 371:1-372:3 (Durette).)

78. Dr. Durette acknowledged that he did not make that narrowing amendment until 18 days after publication of the Clark patent application, which provided the structure, synthesis scheme and activity data for PSI-6130. (Trial Tr. at 369:25-370:14, 389:25-390:14 (Durette).)

79. The Examiner had not asked him to make this narrowing amendment, but he chose to do it of his own accord. (Trial Tr. at 372:18-23 (Durette).)

80. Dr. Durette's explanation that he filed this narrowing amendment simply to "expedite" prosecution (Trial Tr. at 374:7-25 (Durette)), when no such expediting was requested by the Examiner, is not credible.

81. Dr. Durette's explanation that he amended the claims to focus on "subject matter that was ***most important*** to the [Merck-Isis] collaboration" is not credible. (Trial Tr. at 404:14-19 (Durette) (emphasis added).)

82. Dr. Durette's amendment removed all subject matter that Merck and Isis had made or tested as of January 18, 2002. (ECF No. 300.)

83. Dr. Durette's new claims drafted in 2005 cover not a single compound made or tested by Merck and Isis during the entire Merck-Isis collaboration. (*Id.*)

84. Dr. Durette chose to narrow Merck's claims in an attempt to cover PSI-6130, the structure that he learned of on the confidential March 17, 2004 call.

ii. Acts Concerning the Related '224 Patent Application

85. Dr. Durette's additional prosecution activities further demonstrate that the February 2005 amendment was spurred not by any invention actually conceived in the Merck-Isis collaboration, but rather by the confidential materials shared with Dr. Durette during the Merck-Pharmasset interactions, namely that Pharmasset was focused on 2' methyl up, 2' fluoro down nucleosides.

86. After obtaining allowance of the '499 patent in May 2005 (EX-0829.1101-.1105), Dr. Durette filed a continuation application (the '224 application) in September 2005 to obtain further claims to 2' methyl up, 2' fluoro down nucleoside analogs. (EX-0158.) The difference between the '224 application claims and those that ultimately issued as the '499 patent are that the '499 patent covers single-ring base nucleoside analogs, while the '224 application claims cover double-ring base nucleoside analogs with the 2' methyl up, 2' fluoro down configuration. (Ex. 0158 at 222-23 (preliminary amendment).)

87. A different examiner was assigned to review the '224 application than was assigned to review the application that led to the '499 patent. (*Compare* EX-0829.1105 (Elvis Price), *with* EX-0158.0239 (L.E. Crane).) On February 3, 2006, that different examiner rejected the pending claims in the '224 patent application for lack of written description support:

> Claims **32 and 33** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.
>
> The active ingredients required to have anti-HCV activity have not been exemplified within the disclosure (no synthesis reported in the prior art or provided herein) and there is no test data showing that any one of the compounds defined in claim **32** has the anti-HCV activity claimed. And lastly, there is no data which discloses how the compounds of claim **32** may be administered together with the compounds of claim **33** to effectively treat hepatitis C viral infections.

(EX-0158.0236; Durette Dep. Tr. at 79:3-17.)

88. The examiner further stated in this rejection of the pending '224 application claims that "Examiner therefore concludes that the instant claims are directed to subject matter beyond the scope of the instant embodiments and appears to represent new matter." (EX-0158.0236.)

89. On March 15, 2006, Dr. Durette responded to this rejection. In attempting to overcome the rejection, Dr. Durette did not point to anything in the patent application as support

that the 2' methyl up, 2' fluoro down double-ring base compounds he was claiming had activity against HCV. Nor did Dr. Durette point to anything done in the Merck-Isis collaboration. Instead, Dr. Durette pointed the examiner to an article written by Pharmasset as proof that the claimed compounds, including nucleoside analogs with a 2'-methyl up, 2'-fluoro down configuration, were active:

> That certain of the compounds of Claim 32 are active as inhibitors of HCV replication can be gleaned from the publication Bioorg. Med. Chem. Lett., 16:1712-15 (2006), a copy of which is included for reference by the Examiner. Compounds 11, 13 and 14 in the reference are active compounds within the scope of Claim 32.

(EX-0158.0255-257; Durette Dep. Tr. at 82:18-21, 83:7-19.)

90. Based on this statement, Dr. Durette then requested that the examiner withdraw the written description rejection. (EX-0158.0255-257.)

91. Bioorg. Med. Chem. Lett., 16:1712-15 (2006) is an article entitled "Synthesis and antiviral activity of 2'-deoxy-2'-fluoro-2'-C'-methyl purine nucleosides as inhibitors of hepatitis C virus RNA replication." (EX-0159.) The authors are 11 persons from Pharmasset, with the lead author being Jeremy Clark. (*Id.*) Compounds 11, 13, and 14 in the article referenced by Dr. Durette are 2' methyl up, 2' fluoro down nucleosides synthesized and analyzed by the Pharmasset authors and described in the article. None of them had ever been synthesized or tested during the Merck-Isis collaboration. (ECF No. 300; Duffy Dep. Tr. (EX-2382) at 46:22-25; Bennett Dep. Tr. (EX-2381) at 122:24-123:12, 123:15-124:01, 124:06-21.)

92. In response to Dr. Durette's remarks, on May 9, 2006, the examiner maintained the written description rejection. (EX-1058.0261-.0262.) Rather than accepting Dr. Durette's remarks, the Patent Office found that the Pharmasset article referenced by Dr. Durette demonstrated that the application did not have written description support for claims to the 2' methyl up, 2' fluoro down configuration because none of the Pharmasset authors were named as inventors on the '224 application :

> Applicant has supplied Clark et al. (made of record as PTO-892 ref. Y) wherein both the synthesis and the anti-HCV activity disclosures missing from the instant specification may be found. Unfortunately, there is no co-author listed on the publication either employed by instant assignee or listed as a co-inventor herein. Therefore, the instant noted reference is deemed to support the conclusion of the instant rejection, namely that instant applicant did not have possession of the instant claimed invention at the time of filing. Therefore, the instant rejection has been maintained.

(EX-0158.0262; Durette Dep. Tr. at 91:3-21.)

93. In response to the maintained rejection, Dr. Durette requested and received permission to interview the Examiner. In an interview summary prepared by the examiner, the examiner reported that Dr. Durette again relied on the Clark reference as support for the activity of the claimed compounds as methods of treating HCV. (EX-0158.0273.) The examiner maintained the written description rejection.

94. Thereafter, Dr. Durette made further arguments in support of the written description of the pending claim, and conducted multiple additional interviews. (EX-0158.0281, .0288-89, .0303, .0305.) In the final of these interviews on August 30, 2006, the examiner requested that, if applicants could provide a declaration showing that a representative sample of claimed compounds had been tested and showed HCV activity at the time of filing in 2002, then the claims might be allowed. (EX-0158.0306.)

95. Dr. Durette did not respond to this request, and Dr. Durette abandoned the application in January 2007 in the face of a final rejection for lack of written description support. (EX-0158.0298, .0311-12.)

96. Dr. Durette did not respond because Merck had no results to report, as Merck did not conduct any testing of any 2' methyl up, 2' fluoro down compounds until August 2005. (Duffy Dep. Tr. (EX-2382) at 46:22-25; Trial Tr. at 576:1-22 (Seeger).)

97. Dr. Durette's reliance on Pharmasset's work in support of this additional patent application demonstrates that his judgment was, in fact, tainted as to what claims to pursue, as stated at his deposition.

98. Dr. Durette's persistence in attempting to obtain claims to compounds never made or tested in the Merck-Isis collaboration demonstrates that his conduct in not removing himself from prosecution after being exposed to Pharmasset's confidential information violates established norms of behavior in the pursuit of patent rights.

99. After abandoning the '224 application, in February 2007, Dr. Durette filed the patent application that would issue as the '712 patent (the "'712 application"). (Bergman Dep. Tr. (EX-2375) at 26:16-24, 27:03-06; EX-0192.0003.)

100. A different patent examiner than the examiner for the '224 application was assigned to review the '712 application. (EX-0002 (Travis C McIntosh III).)

C. Merck-Pharmasset Interactions in 2008-2010

101. While the '712 application was pending at the Patent Office, Merck made several attempts to license sofosbuvir or acquire Pharmasset.

102. In October 2008, Merck sent a letter to Pharmasset enclosing both a licensing proposal with Pharmasset and an acquisition offer. (Trial Tr. at 1503:19-22 (Demain); EX-1768.0001.)

103. Merck's licensing proposal concerned "Pharmasset's HCV nucleoside inhibitor program," including PSI-7851, the mixture of diastereoisomers, PSI-7976 and PSI-7977 (sofosbuvir), and other drugs. (EX-1768.0001.)

104. Merck offered $625 million to acquire Pharmasset in October 2008. (EX-1768.0002.) In offering to acquire Pharmasset, Merck did not raise with Pharmasset the issue of its intellectual property covering PSI-7851, sofosbuvir, or any of Pharmasset's other HCV nucleoside inhibitors. (Trial Tr. at 1504:8-19 (Demain); EX-1768.)

105. Merck and Pharmasset did not enter into a licensing or acquisition arrangement in 2008, but Merck left open the possibility for further "licensing discussions at some point in the future." (EX-0094.0002.) Merck did not raise the '499 patent, which had issued in 2006, with Pharmasset during the parties' negotiations, did not allege that any Pharmasset compounds

would infringe the '499 patent or that Pharmasset would need to take a license to the '499 patent, and did not cite the '499 patent or any other intellectual property as a reason for not reaching agreement with Pharmasset. (EX-0094.0002; EX-1768.)

106. In the summer of 2010, Pharmasset and Merck entered into licensing and collaboration discussions regarding sofosbuvir (PSI-7977).

107. In July 2010, Pamela Demain sent Pharmasset a proposed term sheet entitled "Licensing and Collaboration Proposal for PSI-7977." (EX-2390.)

108. In that proposal, Merck defined the "Licensed Compound" as "Pharmasset's proprietary nucleotide analogs of natural uridine with the sugar ring having a 2'-deoxy-2'-fluoro-2'-*C*-methyl di-substitution as a mono-, di-, or triphosphate and their prodrugs, " which included PSI-7977, the subject of the licensing proposal. (EX-2390; Trial Tr. at 1509:6-1510:4 (Demain).)

109. In September 2010, the discussions between Merck and Pharmasset culminated in Merck offering to acquire Pharmasset outright for $1.3-1.4 billion. (EX-0069.0001.)

110. Merck made the acquisition offer to "develop and commercialize Pharmasset's line of prodrugs for the prevention and treatment of HCV, including Pharmasset's R7128, PSI-7977 and PSI-938." (EX-0069.0001.) Merck's offer letter did not claim to have invented or to own sofosbuvir. (*Id.*)

111. Merck acknowledged that sofosbuvir (PSI-7977) was in "Pharmasset's line of prodrugs for the prevention and treatment of HCV." (*Id.*)

112. Merck's goal in offering to acquire Pharmasset was to obtain sofosbuvir (PSI-7977). (Pomerantz Dep. Tr. (EX-2387) at 59:5-13, 75:18-23; EX-0066.0007.) At the time of its 2010 acquisition offer, Merck knew the structure of sofosbuvir and was aware that the '499 patent generically covered the structure of sofosbuvir. (Pomerantz Dep. Tr. (EX-2387) at 104:10-24.)

113. Pharmasset's CEO, Schaefer Price, rejected Merck's acquisition offer upon its presentation by Dr. Pomerantz, Merck's head of infectious diseases at that time. (Pomerantz Dep. Tr. (EX-2387) at 106:12-107:6.)

114. Only after Pharmasset rejected its acquisition offer, did Merck inform Pharmasset for the first time that Merck believed the '499 patent covered Pharmasset's technology. (Price Dep. Tr. (EX-2392) at 115:13-116:19.)

115. Mr. Price responded by stating that Pharmasset believed Merck's allegation to be unsubstantiated, and that Pharmasset believed the '499 patent to be invalid for a number of reasons. (*Id*. at 115:6-116:6.)

116. Thereafter, Merck did not make any further allegations that sofosbuvir would infringe the '499 patent or that Pharmasset would need to take a license to the '499 patent, and did not cite the '499 patent or any other Merck intellectual property as a reason for not reaching a licensing or acquisition agreement with Pharmasset.

117. In 2011, Merck considered purchasing Pharmasset for at least $7 billion. (EX-0066; Pomerantz Dep. Tr. (EX-2387) at 139:7-14.)

118. At the time Merck was considering making an offer to acquire Pharmasset in 2011, Merck knew the structure of sofosbuvir (EX-0077.0019), and had previously alleged to Pharmasset that the '499 patent covered sofosbuvir. (Pomerantz Dep. Tr. (EX-2387) at 104:10-24; Price Dep. Tr. (EX-2392) at 115:13-116:19.)

119. Merck ultimately did not make an offer to acquire Pharmasset in 2011. (Pomerantz Dep. Tr. (EX-2387) at 140:17-22.)

120. As Dr. Pomerantz testified, Merck's decision not to make another acquisition offer was because Merck executives could not "pull the trigger" on offering a competitive bid for Pharmasset. (Pomerantz Dep. Tr. (EX-2387) at 140:23-141:17.)

121. Merck's decision to not make another attempt to acquire Pharmasset did not relate to any allegation that the '499 patent covered sofosbuvir. (Pomerantz Dep. Tr. (EX-2387) at 141:15-142:10, 148:21-149:11, 151:3-12.)

122. Gilead announced that it was acquiring Pharmasset on November 21, 2011, for $11 billion. (EX-1098.)

D. Merck's Prosecution of the '712 Patent

123. By January 2011, while Merck was still attempting to acquire Pharmasset, no prosecution had taken place in the '712 application that Dr. Durette filed in 2007 after abandoning the '224 application. (EX-0192.0249; Bergman Dep. Tr. (EX-2375) at 48:20-49:6.)

124. Dr. Durette retired in 2010. (Trial Tr. at 413:20-21 (Durette).) In his place, Merck patent attorney Jeffrey Bergman ultimately became responsible for prosecuting the '712 application. (Bergman Dep. Tr. (EX-2375) at 20:6-8.)

125. In addition to serving as a patent attorney, Mr. Bergman's job responsibilities involved conducting due diligence, including due diligence of Pharmasset when Merck was considering purchasing Pharmasset. (Bergman Dep. Tr. (EX-2375) at 8:11-14, 8:19-21.)

126. Mr. Bergman was involved in Merck's due diligence of Pharmasset at least by the end of 2011, and was aware that Gilead, not Merck, had acquired Pharmasset and sofosbuvir. (Bergman Dep. Tr. (EX-2375) at 9:18-21, 52:8-12, 52:14-17, 52:19-22, 55:7-11, 68:5-10.)

127. In July 2011, Mr. Bergman began adding new claims to the '712 application. (Bergman Dep. Tr. (EX-2375) at 57:5-17; EX-0192.0250-.0266.)

128. In January 2012, Isis sent Merck a letter notifying Merck that it believed that the development of Pharmasset's 7977 (sofosbuvir) for the treatment of HCV infection was encompassed by the claims of the '499 patent. (MERCK0190206-211.) Attached to that letter was a Pharmasset press release announcing that Gilead would acquire Pharmasset for approximately $11 billion. (*Id.*)

129. Pamela Demain and Merck patent attorney Bill Krovatin were recipients of that January 2012 notice letter. (MERCK0190203-204.)

130. Two months later, in March 2012, Mr. Bergman added new claims to the pending '712 application. (EX-0192.0314; Bergman Dep. Tr. (EX-2375) at 70:12-16, 70:20-21.)

131. The new compound claims covered the structural configuration of sofosbuvir's diphosphate and triphosphate metabolites. (Bergman Dep. Tr. (EX-2375) at 70:12-71:6, 71:14-17, 71:21-22; EX-0192.0311-13.) Those claims were also narrower than the previously pending claims. (Bergman Dep. Tr. (EX-2375) at 71:3-6.)

132. Mr. Bergman was aware of the structure of sofosbuvir when he added the claims. (Bergman Dep. Tr. (EX-2375) at 71:24-72:2.)

133. The '712 application did not publish until June 28, 2012, over five years after it was filed by Dr. Durette in February 2007. (Bergman Dep. Tr. at 86:7-9; EX-0002.) As a result, no one outside of Merck was aware of that application until it published. (Bergman Dep. Tr. at 82:22-83:6.)

134. In June 2013, Merck and Isis entered into an agreement renewing their collaboration, which had ended in 2003. (Trial Tr. at 1530:22-1531:22 (Demain); EX-1472; EX-1487.)

135. The purpose of the renewed collaboration was to bring an infringement lawsuit against Gilead and sofosbuvir. (Trial Tr. at 1530:22-1531:22 (Demain); EX-1472.)

136. Among the individuals involved in the renewed collaboration discussions was Shelden O. Heber, a Merck patent attorney who also had responsibility for prosecuting the '712 application. (EX-1472; EX-0002.)

137. The '712 patent issued on July 9, 2013. (EX-0002.) During prosecution, neither Mr. Bergman nor Dr. Durette informed the patent office of the prosecution of the related '224 application, which was abandoned in the face of a written description rejection.

II. [PROPOSED] CONCLUSIONS OF LAW

A. Unclean Hands

138. The doctrine of unclean hands "is rooted in the historical concept of court of equity as a vehicle for affirmatively enforcing the requirements of conscience and good faith. . . . Thus while equity does not demand that its suitors shall have led blameless lives, as to other matters, it does require that they shall have acted fairly and without fraud or deceit as to the controversy in issue." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-15 (1945) (internal quotation marks and citations omitted).

139. The equitable doctrine of "unclean hands" bars a patentee's recovery against an accused infringer if "some unconscionable act of [the patentee] has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation." *Aristocrat Techs. v. Int'l Game Tech.*, No. C-06-03717 RMW, 2010 WL 2486194, at *2 (N.D. Cal. June 15, 2010) (quoting *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933)); *see also Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 251 (1944) (reversing finding of patent infringement and ordering judgment be set aside due to plaintiff's presentation of false testimony and fabrication of evidence); *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 247 (1933) (affirming dismissal of patent infringement case where the patentee had unclean hands due to its presentation of false testimony); *Mas v. Coca-Cola Co.*, 163 F.2d 505, 511 (4th Cir. 1947) (finding the plaintiff had unclean hands and upholding dismissal of plaintiff's suit where plaintiff lied to the Patent Office and fabricated evidence); *id.* ("No court of equity ought to be required to listen to a man whose very presence suggests danger to the administration of justice and whose past conduct affecting the matter in litigation would cast doubt upon the ability of the court to ascertain from him the truth with respect thereto.").

140. In establishing the applicability of the doctrine, the court is "not bound by formula or restrained by any limitation." *Keystone Driller*, 290 U.S. at 245-46.

141. To invoke the doctrine, "one's misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character." *Precision Instrument*, 324 U.S. at 815.

142. "Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim . . . ." *Id.*

143. Unlike inequitable conduct, the doctrine of unclean hands does "not present any standard for materiality." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (2011).

144. "The possession and assertion of patent rights are issues of great moment to the public. . . . The public policy against the assertion and enforcement of patent claims infected with fraud and perjury is too great to be overridden . . . ." *Precision Instrument*, 324 U.S. at 815, 819.

145. A party must prove unclean hands by clear and convincing evidence. 4 Annotated Patent Digest § 27:130; *see Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1374 (Fed. Cir. 2001) (finding clear and convincing evidence that patentee had fabricated lab notebook pages and affirming district court's finding of unclean hands).

146. In this case, numerous unconscionable acts lead the Court to conclude that the doctrine of unclean hands bars Merck's recovery against Gilead for infringement of the '499 and '712 patents. The reasons for this conclusion are as follows.

147. The first set of unconscionable acts barring Merck's recovery from Gilead for infringement concerns the actions of Merck's patent prosecutor, Dr. Durette, in learning the confidential structure of Pharmasset compound PSI-6130 and pursuing patent claims to cover that compound. Specifically, it was an unconscionable act for Dr. Durette, who was responsible for prosecuting patents relating to the Merck-Isis collaboration, to participate on a conference call with Pharmasset where it was known in advance that he would learn the full structure of Pharmasset compound PSI-6130—a structure that Pharmasset guarded closely and would only

agree to reveal under specific, confidential conditions including a firewall, and a compound that Merck knew was an NS5B polymerase inhibitor just like the compounds that were the subject of the Merck-Isis collaboration for which Dr. Durette was seeking patent protection.

148. A related unconscionable act is that on that call, Dr. Durette communicated to Pharmasset that he was within the firewall when, in fact, he was not, and only communicated to Pharmasset that he was prosecuting patents related to the Merck-Isis collaboration *after* learning the full structure of PSI-6130 from Pharmasset.

149. Another unconscionable act is that Dr. Durette did not recuse himself from prosecuting the Merck-Isis patents after learning the full structure of PSI-6130 in violation of both the Pharmasset firewall and Merck policies prohibiting Merck patent prosecutors from participating in licensing discussions in a related area: here, nucleoside analogs as NS5B polymerase inhibitors.

150. An additional unconscionable act is Dr. Durette's pursuit of claims covering Pharmasset's 2' methyl up, 2' fluoro down nucleoside compounds without disclosing to the Patent Office that he first learned the structure and activity of the compounds he was claiming through confidential discussions with Pharmasset, and not through the publication of Pharmasset's patent application, just weeks before he drafted two new, narrow claims.

151. A related unconscionable act is Dr. Durette's representation to the Patent Office that the two new claims he presented for prosecution did not present new matter because they were fully supported by the specification when persons of ordinary skill in the art would have reached the opposite conclusion, as evidenced by the uncontradicted expert testimony of Dr. Secrist presented at trial, and the course of conduct in the prosecution of the '224 application.

152. Each of the foregoing unconscionable acts have an "immediate and necessary relation to . . . the matter in litigation" because the patents that resulted from this series of unconscionable acts are now asserted against Gilead: Pharmasset's successor-in-interest. *See Keystone Driller*, 290 U.S. at 245.

153. The Court concludes that the doctrine of unclean hands additionally bars Merck's recovery against Gilead for infringement of the '499 and '712 patents based on additional unconscionable acts by Dr. Durette relating to his testimony in this case. As outlined below, the record shows that Dr. Durette presented inconsistent, contradictory, and untruthful testimony which additionally leads the Court to conclude that the doctrine of unclean hands has been satisfied here.

154. In particular, Dr. Durette denied unequivocally under oath at his deposition that he was on the conference call with Pharmasset where the full structure of PSI-6130 was disclosed. Yet at trial, Dr. Durette changed his testimony and acknowledged being on that call once he learned that both contemporaneous notes and a live witness (Mr. Roemer) in fact placed him on that call.

155. In addition, Dr. Durette's testimony at trial was not forthcoming or credible as to why he participated on the conference call with Pharmasset, why he denied participating on that call at his deposition, and why during prosecution he cancelled all claims in favor of new claims that covered PSI-6130.

156. The Court concludes that Dr. Durette's testimony amounts to an unconscionable act in that Dr. Durette was not forthcoming and acted with deceit with respect to his role in both learning the confidential structure of PSI-6130 and in pursuing claims at the Patent Office. The Court again concludes that Dr. Durette's testimony has an "immediate and necessary relation to . . . the matter in litigation" because the patents that resulted from this series of unconscionable acts are now asserted against Gilead: Pharmasset's successor-in-interest. *Keystone Driller*, 290 U.S. at 245.

157. The Court concludes that the doctrine of unclean hands also bars Merck's recovery against Gilead for infringement of the '499 and '712 patents based on additional unconscionable acts relating to the procurement of the '712 patent, as outlined below.

158. Specifically, knowing that Pharmasset believed the '499 patent invalid, knowing the structure of sofosbuvir, and knowing that Merck would never commercialize sofosbuvir, Merck patent attorney Jeffrey Bergman drafted patent claims in 2012 to encompass sofosbuvir over a decade after the original Merck-Isis patent application was originally filed in 2002. The Court finds these claims were prosecuted after the Patent Office had concluded, when presented with the related '224 application, that there was no written description support in the specification for the compounds that Pharmasset's Jeremy Clark had invented; namely, nucleoside analogs with a 2' methyl up, 2' fluoro down configuration.

159. The Court also finds that Mr. Bergman's patent prosecution activities were part of a calculated strategy by Isis and Merck, including Mr. Sheldon Heber who had shared responsibility for prosecuting the '712 application, to draft claims that would encompass sofosbuvir, despite knowing that the claims lacked written description support, to obtain an additional patent to assert in an infringement lawsuit against Gilead.

160. The Court concludes that these acts have an "immediate and necessary relation to . . . the matter in litigation" because the patents that resulted from this series of unconscionable acts are now asserted against Gilead: Pharmasset's successor-in-interest. *Keystone Driller*, 290 U.S. at 245.

161. For the foregoing reasons, the doctrine of unclean hands bars Merck's recovery against Gilead for infringement of the '499 and '712 patents.

B. Waiver

162. A patentee impliedly waives its right to enforce a patent against an accused infringer where the patentee's "conduct was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished." *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1348 (Fed. Cir. 2011).

163. A patentee's waiver effectively creates an implied license for the accused infringer to make, use, or sell the patented invention. *See Hynix Semiconductor Inc. v. Rambus*

Inc., 609 F. Supp. 2d 988, 1030 (N.D. Cal. 2009) (citing *Wang Labs., Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1580 (Fed. Cir. 1997)).

164. A patentee has the "exclusive right to practice [its] invention." *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989) (citing 35 U.S.C. § 154).

165. A party must prove waiver by a preponderance of the evidence. *Oracle Am., Inc. v. Google Inc.*, No. C 10-03561 WHA, 2012 WL 1965778, at *2 (N.D. Cal. May 31, 2012).

166. Merck's efforts to license from and/or acquire Pharmasset in order to gain access to compounds already falling within the scope of its '499 and '712 patents (PSI-6130 and PSI-7977) was fundamentally inconsistent with an intent to enforce its patent rights. *See Hynix Semiconductor*, 645 F.3d at 1348.

167. It was reasonable for Pharmasset and Gilead to believe that Merck, as the patent-holder, knew the scope of its claimed invention and had relinquished its enforcement rights.

168. Merck impliedly waived the right to assert the '499 and '712 patents against Gilead.

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